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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,235	04/29/2005	Masaya Nishio	271564US0PCT	5068

22850 7590 05/27/2010  
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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WESTERBERG, NISSA M

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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05/27/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
oblonpat@oblon.com  
jgardner@oblon.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,235	<b>Applicant(s)</b> NISHIO, MASAYA	
	<b>Examiner</b> Nissa M. Westerberg	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 March 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12 and 20-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12 and 20-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicants' arguments, filed March 4, 2010, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

#### ***Response to Amendment***

2. The declaration under 37 CFR 1.132 filed March 4, 2010 is insufficient to overcome the rejection of claims 12 and 20 – 36 under 35 U.S.C. 103(a) as being unpatentable over JP 07-277923 in view of Nakanishi (US 2002/0131947) and the International Cosmetic Ingredient Dictionary and Handbook (7th edition,, 1997; p 1656 - 1657, 1667 – 1669; "ICIDH") because: the data presented therein does not establish the criticality of the particular amount and ingredients of component (B-2) for the full breadth of the instant claims. All of the comparisons make use of one particular methylpolysiloxane and one particular liquid paraffin (ingredients 5 and 7 from the list on page 5 of the declaration). For all of the compositions, equal amounts of the methylpolysiloxane and liquid paraffin are used. Component (B-2) as set forth in the claims just must be present in an amount ranging from 30 to 60%, and the methylpolysiloxane and liquid paraffin do not need to be present in equal amounts, as in all of the formulations set forth in the declaration. Also, as can be seen from the table presenting the various formulations, there are multiple types of both polymethylsiloxane

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and liquid paraffin which are available. These data only relate to a particular type of each of these ingredients. Thus, these data do not demonstrate the criticality of the amount of component (B-2) for the full breadth of compositions encompassed by the instant claims.

***Claim Rejections - 35 USC § 112 – 2<sup>nd</sup> Paragraph***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 12 and 20 – 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 19, 2009 and those set forth below. The amendments to the claims have clarified that the amounts of components (B-1) and (B-2) in independent claim 12 are based on the weight of the liquid skin protective composition. However, the basis of the weigh percent for ingredient (A) in claim 12 and all ingredients in independent claim 26 remain unclear. Therefore, this rejection is maintained.

5. Claims 26 – 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what the acceptable range for the

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volatility of component (B-1) in the limitation “not less than 0.2-50 mg/cm<sup>3</sup>hr”. Generally, ranges stand alone but the inclusion of the phrase “not less than” leads to confusion as to whether additional values outside the range are encompassed. Please clarify.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 12 and 20 – 36 were rejected under 35 U.S.C. 103(a) as being unpatentable over JP 07-277923 in view of Nakanishi (US 2002/0131947) and the International Cosmetic Ingredient Dictionary and Handbook (7th edition, 1997; p 1656 - 1657, 1667 – 1669; “ICIDH”). This rejection is maintained for the reasons of record set forth in the Office Action mailed October 19, 2009 and those set forth below.

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Applicant traverses this rejection on the grounds that the cited art does not disclose, suggest or provide a reasonable expectation of success for a composition in (B-2) contains methylpolysiloxane and liquid paraffin having a volatility of not more than  $0.1 \text{ mg/cm}^3\text{hr}$  and a mutual solubility of 10% or less, which results in superior properties caused by phase separation after evaporation of the more volatile ingredients. These arguments are unpersuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a mutual solubility of 10% or less) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As methylpolysiloxane and liquid paraffin are genera of compounds, it is unclear if all combinations of these ingredients exhibit this mutual solubility or if only certain combinations of methylpolysiloxanes and liquid paraffins possess this mutual solubility. Additionally, the products described in Nakanishi can be used as oil bases for cosmetic products. In example 22, decamethylpentacyclopentasiloxane (10%), methylphenylsiloxane (3%) and liquid paraffin (5%) are combined to form the oil base for an emulsion based moisturizing cream ([0291] - [0300], percentages based on weight of final emulsion). This composition also does not contain a monovalent alcohol having from 1 to 4 carbon atoms (1,2-butylene glycol is not monovalent and PEG-400 has more than 4 carbon atoms). The first ingredient corresponds to B1 of the instant claims being a cyclic

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methylcyclopolsiloxane. The ratio of that to the liquid paraffin is 2/1, which falls within the range recited in new claim 30.

Applicant also argues that none of the prior art appreciated the selection and the amounts of the various ingredients as recited in the various claims that provides superior functionality. These arguments are unpersuasive. While the applied prior art does not provide the volatility of each of these ingredients, the formulations appear similar to those used by Applicant and particularly for the oil based formulations of Nakanishi that used a combination of ingredients in amounts (when used as an oil base with 0% water (¶ [0080]) are not significantly different from those recited in the instant claims. That correspondence, along with the lack of data showing the superior performance of the composition for non-equal amounts of B1 and B2 with different members of the genera of possible components B1 and B2 are insufficient to establish the unexpectedly superior properties of the instant composition with the particular ranges for the components A, B1 and B2.

Applicant also argues that there are no results-effective variables pointed out in the prior art for the selection of the various components. This argument is unpersuasive. The cited prior art teaches the use of variety of components such as those recited by the instant claims and comes close to the amounts of these ingredients when used as an oil base alone and not further processed into an emulsion. The prior art does not need to explicitly identify the ingredients and amounts of the various ingredients when one of ordinary skill in the art would know that the amount of those ingredients can be varied in order to provide the desired consistency for the final product. As previously

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pointed out, a lipstick is designed to be applied to a small area of the skin and spraying is not an optimal application route. The cited prior art discloses that these compositions can also be used as lotions, for example, which are less viscous than lipstick. The required changes (e.g., lesser amounts of high viscosity compounds or increased amounts of low viscosity compounds) are within the knowledge and skill of one of ordinary skill in the cosmetic formulation art to produce a formulation with the required characteristics in terms of intended use of the product and the optimal way in which the product can be used (e.g., spraying onto the skin to effect the application of the composition quickly to large areas of the skin). So while not explicitly identified as such by the cited prior art, the selection and amounts of these ingredients are results effective parameters.

Applicant states that no support has been pointed out for limiting water content in the sprayable formulations to 10 wt% or less. Support for compositions lacking water has been pointed out. the exemplary composition prepared in the JP reference do not contain any water (see p 6 of October 19, 2009 Office Action) and Nakanishi discloses that the cosmetic composition can contain from 0 - 90% water (§ [0080]).

In regards to the new claims, while a powder or colorant can be used in the cosmetic composition (§ [0081]), the presence of inorganic powders or pigments is not required. To obtain a colored composition organic powders may be used (§ [0085]) non-colored products would be obtained if no such powders or pigments were used. The inclusion of powders or pigments will depend on the intended use of the product – e.g., cosmetic foundation is generally colored while moisturizing lotion generally does not



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contain powders or pigments. Nakanishi also discloses that antiseptics and preservative, which read on anti-microbial agents, and antioxidants, which are encompassed by anti-inflammatory agents, may be used in the cosmetic compositions ([0101], [0105], [0106]). It would have been obvious to one of ordinary skill in the art to exclude inorganic pigments or powder and to include anti-microbial agents and/or anti-inflammatories depending on the particular requirements of the cosmetic formulation being prepared.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/  
Primary Examiner, Art Unit 1618

NMW